

## **Helioseal F Sealant / Ivoclar Vivadent, Inc./ RECALL (11/15)**

### **Reason/Information:**

Ivoclar Vivadent issued an Urgent Medical Device Recall on the following materiel. Reason: A defect occurred in the production process of Helioseal F Sealant; the particles in the faulty component seem to be larger than the size defined in the formula. This results in difficulties during extrusion of the materiel.

### **Disposition/Instructions:**

Actions to be taken by the customer:

--Check Inventory for the affected lot number/materiel. Notify Ivoclar Vivadent Customer Service at 800-533-6825 about the quantities of the affected lot number/materiels.

--Complete, sign and return the acknowledgement form and return it to Ivoclar Vivadent by fax 716-691-2294 or e-mail at [recall.us@ivoclarvivadent.com](mailto:recall.us@ivoclarvivadent.com)

--Contact Ivoclar Vivadent Customer Service at 800-533-6825 as soon as possible between the hours of 8 a.m. and 6 p.m. (Eastern Standard Time), Monday through Friday and a representative will arrange to pick up customers affected materials for return and credit.

--Notify customers of this issue and return the materiel to Ivoclar. Alternatively, customers may provide Ivoclar with a list of their customers who have received this batch and Ivoclar will notify the customers accordingly. Credit will be issued for all returned materiels. Be sure to mark the returned materiel with the word "RECALL." Replacement materiel is available for order immediately.

Measures taken by the company:

Additional quality controls have been introduced in order to avoid a new occurrence of this defect. Further a detailed root cause analysis has been started to implement the most effective preventive actions for future production processes.

If customers have any questions contact Ivoclar Vivadent Customer Service 800-533-6825. Customers may also call at 716-691-2260 or 716-691-0010.

Affected lot numbers can be found below. Additional information can be found by clicking [here](#).

### **LOT / SN:**

U12511 (Expiration Date - 9 November 2017)

U19925 (Expiration Date - 9 November 2017)